IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, vs. XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	Civil Action No. 1:23-cv-00707

MOTION FOR LEAVE TO FILE BRIEF OF AMICUS CURIAE FRESENIUS KABI IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Proposed amicus curiae, Fresenius Kabi USA, LLC ("Fresenius Kabi") respectfully requests leave to file the attached amicus curiae brief in support of Plaintiffs' motion for summary judgment. Fresenius Kabi has contacted the parties in this matter and Plaintiff Pharmaceutical Manufacturers of America and the Defendants have consented to the filing of this brief, and Plaintiffs National Infusion Center Association and Global Colon Cancer Association have authorized Fresenius Kabi to state that they have no objection to the filing of this brief. In support of this motion, Fresenius Kabi states the following:

1. Fresenius Kabi is a pharmaceutical company with significant activity in selling generic and biosimilar products. Thus, it has unique market perspectives because it competes with brand companies that develop new drugs, some of which Plaintiffs represent, yet still agrees that the Defendants' position contravenes Congress's objectives to provide cost savings to the public. In particular, there are substantial unintended consequences connected with the implementation of the Inflation Reduction Act ("IRA") and associated guidelines, and Fresenius Kabi therefore seeks to provide the Court with further legal, regulatory, and industry perspectives relating to those unintended consequences.

2. There is no apparent Federal Rule of Civil Procedure or Local Rule that controls motions for leave to appear as amicus curiae in this Court. However, "[t]he Court has discretion to consider amicus briefing where the proffered information is timely and useful or otherwise necessary to the administration of justice." *Does 1–7 v. Round Rock Indep. Sch. Dist.*, 540 F. Supp. 2d 735, 738 n.2 (W.D. Tex. 2007); *see also Club v. Fed. Emergency Mgmt. Agency*, No. CIV.A. H-07-0608, 2007 WL 3472851, at *1 (S.D. Tex. Nov. 14, 2007) (*quoting Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 36 (M.D. Pa. 1995)). The role of amici is to assist the court "in cases of general public interest by making suggestions to the court, by providing supplementary assistance to existing counsel, and by insuring a complete and plenary presentation of difficult issues so that the court may reach a proper decision." *Newark Branch, N.A.A.C.P. v. Town of Harrison, N.J.*, 940 F.2d 792, 808 (3d Cir. 1991). Amicus briefs should be allowed "when the amicus has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide." *Ryan v. Cmty. Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997) (citation omitted).

3. Fresenius Kabi offers an important perspective on the impact of the IRA and its

Guidelines on the generic and biosimilar industry and market prices, as well as on the regulatory implications of the Guidelines. Although Congress and Defendants may have been well intended in passing the IRA, the way it is structured disincentivizes generic and biosimilar manufacturers from developing lower-cost version of approved medications. This impacts both the price that Government and private consumers pay and the availability of important drugs.

4. The IRA and associated guidelines also include substantial loopholes, which then invite further problems based on arbitrary and ever-changing standards that Defendants have yet to deinfe. For example, the "bona fide marketing" standard requires some unknown thresholds of activity, and if the initial branded company marketing a drug does not meet that standard—or worse if CMS does not make a timely determination—then that drug will be on the required negotiation list. The structure therefore makes worse an underlying problem that CMS recognizes: the IRA will lead to limited launch and other gamesmanship settlements that will inhibit true competition and will harm consumers in the long run.

5. If the Court grants the Fresenius Kabi's Motion to participate as amicus and accepts its brief for filing, the parties would have an adequate opportunity to respond. Defendants' opposition brief and cross motion for summary judgment is due September 29, 2023, and Plaintiffs' reply brief in support of its motion for summary judgment and its opposition to Defendants' cross motion for summary judgment is due October 26, 2023. There is sufficient time under this schedule for the parties to address the related issues raised by Fresenius Kabi.

For these reasons, proposed amicus Fresenius Kabi respectfully requests that they be granted leave to file the attached amicus curiae brief.

Dated: August 28, 2023

Respectfully submitted,

/s/Imron T. Aly
Imron T. Aly (Admitted in W.D. Tex.)
Kevin M. Nelson
Joel M. Wallace
ARENTFOX SCHIFF LLC
233 S. Wacker Dr.
Suite 7100
Chicago, IL 60606
312.258.5500
imron.aly@afslaw.com
kevin.nelson@afslaw.com
joel.wallace@afslaw.com

Attorneys for Amicus Curiae
Fresenius Kabi USA, LLC

CERTIFICATE OF SERVICE

I hereby certify that on the 28th day of August, 2023, I electronically filed and served the foregoing document with the Clerk of the Court using the CM/ECF system which to my understanding and experience will send notification of such filing to all counsel whom have consented to electronic service.

August 28, 2023 __*Imron Aly*_____
Imron Aly